



U.S. Department of Justice

*United States Attorney
Eastern District of Wisconsin*

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NEWS SUMMARY:

Gerald Dorros, MD (dob 5/9/1942), a cardiologist who formerly lived and practiced in Milwaukee, was charged today with a misdemeanor violation of federal law for shipping and using a medical device that had not been approved for such use by the Food and Drug Administration (FDA). The device in question was an investigational stent-graft device manufactured in Argentina and used to attempt to repair aortic aneurysms. Also filed today was a plea agreement that was reached with Dr. Dorros, who now resides in Wyoming, under which he agreed to plead guilty to this charge.

Under the terms of the plea agreement, the parties are jointly recommending that Dr. Dorros be placed on probation for two years, during which time he will perform 200 hours of community service, and pay a fine of \$5000. Also reached in connection with this case are separate settlement agreements between the United States and Dr. Dorros.

These agreements include a settlement agreement with the U.S. Department of Justice and the Department of Health and Human Services to resolve any potential claim the United States may have under the False Claims Act for medical procedures Dr. Dorros, which were performed using unapproved medical devices, that were paid for by the Medicare program. Under this agreement, Dr. Dorros will pay the United States \$1,065,000 and enter into an individual Integrity Agreement to ensure similar billing does not re-occur.

In addition, Dr. Dorros entered into an agreement with the FDA under which he will pay \$30,000 to the FDA to resolve any civil claims the FDA may have for his use of unapproved medical devices.

In related matters, the United States previously reached civil settlements with two Milwaukee hospitals and Wisconsin Heart and Vascular, S.C. related to claims submitted to Medicare for procedures performed by Dr. Dorros. The two hospitals are Aurora Health Care Metro, Inc., doing business as St. Luke's Medical Center, and Aurora Sinai Medical Center. Under the terms of these settlements, St. Luke's and Aurora Sinai paid \$2,200,000, and Wisconsin Heart and Vascular paid \$163,331.51 to the United States to resolve potential liability under the False Claims Act. In addition, St. Luke's and Wisconsin Heart and Vascular have each agreed to compliance provisions as part of their respective civil settlements. These provisions seek to monitor certain future billings to Medicare by these medical providers and are implemented and monitored by the United States Department of Health and Human Services, Office of the Inspector General. Wisconsin Heart and Vascular and the hospitals have denied any wrong-doing in this matter and have both cooperated in the government's investigation.

These settlements resolve the government's civil investigation into allegations that Medicare was improperly billed for medical procedures performed by Dr. Dorros at St. Luke's Hospital and Aurora Sinai (formerly known as Sinai Samaritan Hospital) which involved the use of certain devices that were not approved by the United States Food and Drug Administration. Primarily at issue were procedures performed by Dr. Dorros at St. Luke's between 1994 and 2000 that used investigational stent-graft devices, that were manufactured in Argentina, to repair aortic aneurysms. Wisconsin Heart and Vascular employed Dr. Dorros during part of the relevant time period and submitted claims to Medicare for Dr. Dorros' services in regards to these procedures. St. Luke's and Sinai submitted claims to Medicare for the hospital charges related to these procedures.

This matter was investigated by the Federal Bureau of Investigation, the Office of the Inspector General for the U.S. Department of Health and Human Services, the U.S. Food and Drug Administration, and U.S. Immigration and Customs Enforcement. The criminal case is assigned to Assistant U.S. Attorney Matthew L. Jacobs for prosecution. The civil matters are assigned to Assistant U.S. Attorneys Stacy Gerber Ward and Christian R. Larsen..

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